**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| IN RE TESTOSTERONE REPLACEMENT THERAPY PRODUCTS LIABILITY LITIGATION | Case Number 14 C 1748<br>MDL 2545<br>Honorable Matthew F. Kennelly |
| This Document Relates to:<br>Case No. 14-cv-1483 (*Cataudella*);<br>Case No. 14-cv-1298 (*Lau*); and<br>Case No. 14-cv-2394 (*Parker*) | |

# PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO MOTION OF DEFENDANTS ENDO PHARMACEUTICALS INC., ELI LILLY AND COMPANY AND LILLY USA, LLC, AND AUXILIUM PHARMACEUTICALS, INC. TO JOIN AND SUPPLEMENT DEFENDANTS' MOTION TO DISMISS COMPLAINTS

August 15, 2014

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## INTRODUCTION

Defendants Endo Pharmaceuticals Inc. ("Endo"), Eli Lilly and Company and Lilly USA, LLC (together "Lilly"), and Auxilium Pharmaceuticals, Inc. ("Auxilium") have joined in the motion to dismiss filed by Defendants AbbVie, Inc. and Abbott Laboratories, Inc. (together "AbbVie"), but also have filed a supplemental motion (the "Supplemental Motion") to dismiss three complaints, *Cataudella v. Abbvie, Inc. et al.*, Case No. 14-cv-1483, *Lau v. AbbVie, Inc. et al.,* Case No. 14-cv-1298, and *Parker v. AbbVie, Inc., et al.,* Case No. 1:14-cv-02394. (Collectively, Endo, Lilly, and Auxilium are referred to as the "Supplemental Defendants.") The Supplemental Motion should be denied for the reasons set forth in Plaintiffs' Memorandum in Opposition to Defendants' Motion to Dismiss ("Plaintiffs' Lead Opposition") and also because, as described below, the allegations in the Amended Complaints filed in *Parker, Cataudella,* and *Lau* sufficiently state against Auxilium, Endo, and Lilly, respectively.

## FACTUAL BACKGROUND

The facts pertaining generally to the approval and marketing (including off-label marketing) of the various testosterone replacement therapy ("TRT") products; the dangerous side effects of those products; the absence of appropriate warnings of those dangers; and the fraudulent conduct through which TRT products were sold are set forth in the Lead Opposition and hereby incorporated by reference. The facts particular to the *Cataudella, Lau*, and *Parker* cases and specific to Endo, Lilly, and Auxilium are set forth in the Amended Complaint ("AC") filed in each case and summarized here for the Court's convenience.

**Natale Cataudella**

Natale Cataudella is a 74-year old man, who sought testing and treatment for "Low T" based on representations and information provided by AbbVie and Endo. *Cataudella* AC ¶ 128-29. Beginning in March, 2013, Cataudella was treated with Fortesta, sold by Endo, and with AndroGel, sold by AbbVie. *Id.* at ¶¶ 133-134. He used these

TRT products until August, 2013, when he was diagnosed with a pulmonary embolism. *Id.* at ¶ 139, 142. Cataudella had no prior history of blood clots. *Id.* at ¶ 128. He continues to suffer from pulmonary impairment and other injuries. *Id.* at 141.

As explained in the *Cataudella* AC, Endo, along with AbbVie, "engaged in an aggressive unbranded 'disease awareness' campaign to alert men that they might be suffering from 'low T,' an abbreviated term for low testosterone." *Id.* at ¶ 7. In addition, Endo's branded marketing campaign for Fortesta was "similar" to AbbVie's campaign for AndroGel." *Id.* Indeed, "[a]fter FDA approval, Fortesta was widely advertised and marketed by Endo as a safe and effective testosterone replacement therapy." *Id.* at ¶ 34. Endo's campaign conflated "hypogonadism," the condition for which Fortesta had been approved, and low testosterone, or "Low T," a non-existent and unrecognized medical condition. *Id.* at ¶¶ 42-47. Plaintiff specifically alleges that "[t]he advertisements disseminated by Endo suggested that various symptoms often associated with other conditions may be caused by low testosterone and encouraged men to discuss testosterone replacement therapy with their doctors if they experienced any of the 'symptoms' of low testosterone." *Id.* at ¶ 47. Plaintiff further alleges that "Endo's national education campaign included the creation and continued operation of the website www.GetTestedForLowT.com." *Id.* at ¶ 48.

In addition to allegations about the conduct of all of the defendants, the *Cataudella* AC contains further specific allegations about Endo, including that "In 2013, Endo spent more than 70% of its $13 million advertising budget for Fortesta on detailing physicians about Fortesta and 'Low T,'" *see Cataudella* AC at ¶ 51, and that "Endo made testing for 'Low T' even more enticing to consumers by providing free blood testing as long as state law didn't prohibit it and the men indicated on an online questionnaire that they had at least two 'symptoms' of 'Low T.'" *Id.* at ¶ 54. Plaintiff also specifically alleges that his "physician would not have prescribed AndroGel *or Fortesta* to his patient, Natale, had he been advised of and warned of the risks of

pulmonary emboli caused by or increased with respect to the risk of harm by AndroGel and *Fortesta*." *Id.* at ¶ 132 (emphasis added). Plaintiff also specifically alleges that the Fortesta he took was "defective due to inadequate warnings and instructions," i*d.* at ¶ 150, and that "Defendants failed to adequately warn consumers and/or their health care providers that while a patient was taking AndroGel and/or Fortesta it was necessary to frequently monitor hematocrit and estradiol levels to prevent heart attacks, strokes, pulmonary embolisms, cardiovascular events and blood clots." Id. at ¶ 152.

**Frank Lau**

Plaintiff Frank Lau is 46 years old, and, prior to his use of TRT products had no history of blood clots or significant cardiovascular problems, *Lau* AC ¶ 125. He "sought specific testing and treatment for 'Low T' based upon the representations and medical information provided to him by AbbVie and Lilly Defendants through direct-to-consumer educational and information 'Low T' awareness campaigns propagated by AbbVie and Lilly Defendants." *Id.* at ¶ 126. He began testosterone therapy in July, 2011, first with Axiron, then with AndroGel. *Id.* at 130. In September, 2011, Lau suffered a stroke. *Id.* at ¶¶ 131-132. He continues to suffer from brain impairment and other injuries. *Id.* at ¶ 134. Plaintiff specifically alleges that he suffered his stroke "[b]ecause of his use of AndroGel and Axiron." *Id.* He further alleges that had he and his physicians "known the true risks associated with the use of testosterone medications, including AndroGel and Axiron, he would not have consumed the AndroGel or Axiron, and/or would have been adequately monitored for its side effects, and as a result, would not have incurred the injuries or damages he did as a result of his use of AndroGel and Axiron." *Id.* at ¶ 140.

As alleged in the *Lau* AC, Lilly engaged in a marketing campaign for Axiron similar to the campaign used by the AbbVie for AndroGel. *Lau* AC ¶ 6. The *Lau* AC also describes the extensive off-label marketing in which Lilly, as well as AbbVie, engaged. For example, "AbbVie and Lilly Defendants' television advertisements

suggest that various symptoms often associated with other conditions may be caused by low testosterone and encourage men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" include less energy, moodiness, low sex drive, and increased body fat —all general symptoms that are often a result of aging, weight gain, or lifestyle, rather than low testosterone." *Lau* AC ¶ 43. Moreover:

> The advertisements disseminated by Lilly suggested that various symptoms often associated with other conditions may be caused by low testosterone and encouraged men to discuss testosterone replacement therapy with their doctors if they experienced any of the "symptoms" of low testosterone. These "symptoms" included "decreased sexual desire (libido)," "erectile dysfunction," "fatigue and loss of energy," "depressed mood," "loss of body hair (decreased need to shave)," "decrease in strength," and "osteoporosis (decreased bone density)." All of these are general symptoms that are often a result of aging, weight gain, or lifestyle, rather than conditions associated with hypogonadism.

*Id.* at ¶ 46. Indeed, Lilly's website makes no attempt to claim that Axiron is intended to treat the actual medical condition of hypogonadism; instead, "[o]n its Axiron.com website, Lilly states: 'Indication: AXIRON is used to treat adult males who have low or no testosterone.'" *Id.* at ¶ 41. 51. Lilly makes Axiron even more enticing to consumers by providing an easily downloadable "Savings Card" which can be used for a free 30-day trial and up to $75 in monthly savings of Axiron. Its Savings Card solicitation fails to mention any step regarding consultation with a physician and diagnoses of hypogonadism and associated conditions. *Id.* at ¶ 51.

Lilly also engaged, along with the sellers of other TRT products, in an unbranded marketing campaign "targeted toward men who do not have Hypogonadism, nor have low or no testosterone in conjunction with associated medical conditions." *Lau* AC at ¶ 42. Defendants' "disease awareness campaigns "consist of television advertisements, promotional literature placed in healthcare providers' offices and distributed to potential AndroGel and Axiron users, and online media including the unbranded

website "IsItLowT.com." *Id.* As explained in the *Lau* AC, Defendants' promotional materials were misleading because they suggested that Defendants' TRT products were "useful in the treatment of a broader range of conditions, or in a broader population of patients, than has been demonstrated by substantial evidence or substantial clinical experience" and because they represented or suggested that these products were "more effective than has been demonstrated by substantial evidence or substantial clinical experience." *Id.* at ¶¶ 71-72. Lilly's and AbbVie's promotional activities were successful: their advertising "paid off in a return of $1.4 billion in AndroGel sales and $178.7 million in Axiron sales during the past year (2013)." *Id*. at ¶ 56.

Neither Lilly nor AbbVie warned the consumers to whom they marketed their TRT products, nor the physicians who prescribed them, of the dangerous side effects of testosterone therapy. *Lau* AC at ¶¶ 100-114. Indeed, "Defendants concealed material relevant information from potential AndroGel and Axiron users, and their physicians, and minimized user and prescriber concern regarding the safety of AndroGel and Axiron, including but not limited to its known propensity to drastically increase hematocrit and estradiol in users." *Id.* at ¶ 105.

**Loran Parker**

Loran Parker used AndroGel and Testim, the TRT product sold by Auxilium for symptoms he attributed to low testosterone as a result of Defendants' advertisements. *Parker* AC ¶ 147. After taking multiples doses of the two products, Parker suffered a myocardial infarction. *Id.* at ¶ 148. 149. The Androgel and Testim that Parker caused physical and emotional impairment which affected his personal and professional life. *Id.* at ¶ 149. Had he and his doctors known the risks of testosterone medications, including specifically AndgroGel and Testim, Parker "would not have consumed the AndroGel and/or Testim, and/or would have been adequately monitored for their side effects, and as a result, would not have incurred the injuries or damages he did as a result of his use of AndroGel and Testim." *Id.* at ¶ 153.

Testim was marketed through a combination of branded and unbranded marketing. For example, Auxilium engaged in direct-to-consumer marketing, promotional, and comprehensive educational campaigns through a variety of educational, advertising, and informational multimedia platforms, including Internet-based dedicated "Low T" and "Testim" websites. *Parker* AC ¶ 42. Specifically, Auxilium retained a marketing company that developed "ePromotion" and "eBrand Messaging" programs for Auxilium. *Id*. at ¶ 43. "The "ePromotion" strategic initiative relied upon promoting Testim to physicians for the treatment of age-related declines in testosterone levels and age-related symptoms in men, thereby encouraging 'off-label' prescribing and 'label expansion' with respect to the Testim product's clinical uses." *Id.* at ¶ 47.

Auxilium also initiated a ""Low Testosterone Therapy With Testim" campaign; that campaign misrepresented to consumers and their physicians that "hypogonadism" is nothing more than low testosterone and is evidenced by symptoms including "reduced sexual function, desire and performance, low energy or fatigue, bad mood or poor concentration, reduced muscle mass/strength and increased body fat." *Parker* AC ¶¶ 48-52. Auxilium also developed its own interactive questionnaire, which invited consumers to self-screen and self-assess for "Low T" signs and symptom patterns. *Id.* at ¶ 57. In fact, Auxilium's questionnaire screened for age-related signs and symptoms, which are not approved clinical indications for androgen therapy. *Id.* at ¶ 58. Moreover, "Auxilium knowingly promoted Testim to physicians as being a treatment for the conditions set forth" on the interactive questionnaire. *Id.* at ¶ 62.

Auxilium also developed a "Level Up Plan, designed to encourage consumers to seek treatment for "Low T," and to bypass the medical judgment of doctors in making this decision. *See Parker* AC ¶¶ 63-67. It further engaged a marketing provider to optimize its web-based Testim campaign. *Id.* at ¶¶68-69. The campaign was designed to (and did) drive consumers to the Testim website through false, inaccurate, deceptive,

and misleading information that conflated the diagnosis of hypogonadism with the "diagnosis" of "Low T" and with aged-related declines in testosterone levels or other age-related symptoms. *Id.*

As alleged in the *Parker* AC, not only did Auxilium (along with AbbVie) market its TRT product for off-label use and misrepresent the condition for which the product had been approved, it also failed adequately to warn consumers and physicians about the dangers of TRT products, including the increased risk of heart attack. *Parker* AC ¶¶ 129-142.

## APPLICABLE LEGAL STANDARDS

On a motion to dismiss under Rule 12(b)(6), the Court "construe[s] the complaint in the light most favorable to the plaintiff, taking as true all well-pleaded factual allegations and making all possible inferences from those allegations in his or her favor." *Wilson v. Price*, 624 F.3d 389, 391 (7th Cir. 2010). "The complaint's allegations must plausibly suggest that the plaintiff has a right to relief, raising that possibility above a 'speculative level'. . . ." *Id*. at 391-92, *citing Tamayo v. Blagojevich*, 526 F.3d 1074, 1084 (7th Cir.2008) (citation omitted). But "the plausibility requirement demands only that a plaintiff provide sufficient detail to present a story that holds together." *Alexander v. United States*, 721 F.3d 418, 422 (7th Cir. 2013). Indeed, Rule 8 requires only that a complaint give "fair notice [to the defendant] of the nature and basis or grounds of the pleader's claim and a general indication of the type of litigation that is involved . . . ." *Swanson v. Citibank, N.A.*, 614 F.3d 400, 404 (7th Cir. 2010); *see also Hahn v. Walsh,* 13-1766, 2014 WL 3906501, *9 (7th Cir. Aug. 12, 2014) *(*"the purpose of Rule 8 is to provide a defendant with fair notice of the claims against him"). A plaintiff is "not required to include detailed factual allegations." *Alexander*, 721 F.3d at 422. Thus, as the Seventh Circuit has explained, the purpose of the "plausibility" requirement is ""in order to assure that a pleading suffices to give effective notice to the opposing party," not in order to evaluate the veracity of the pleaded facts or the ultimate merits of the plaintiff's

claim." *Hahn*, 2014 WL 3906501, *9. Dismissal is proper only "if it appears beyond doubt that the plaintiff cannot prove any facts that would support his claim for relief." *Wilson*, 624 F.3d at 392.

## ARGUMENT

### I. PLAINTIFFS' PLEADINGS ARE SUFFICIENT UNDER RULE 8

Whatever the merits of the Supplemental Defendants' arguments as addressed to Plaintiffs' original pleadings, it is beyond doubt that Plaintiffs' Amended Complaints fully comport with Rule 8 and state claims against Endo, Lilly, and Auxilium. Plaintiffs allege not merely that they took the Supplemental Defendants' products. Rather, as described above, they allege, with specific reference to Endo, Lilly, or Auxilium, as the case may be, that these defendants, as well as AbbVie, (a) engaged in off-label marketing of their TRT products, promoting them for a variety of symptoms of aging, rather than for the medical condition of hypogonadism; (b) misrepresented that hypogonadism was nothing more than low testosterone; and (c) failed adequately to warn of the dangers of testosterone therapy. Plaintiffs' amended pleadings also make clear that all of the defendants engaged in a coordinated, unbranded "disease awareness" campaign designed to create demand for TRT products in healthy aging men. For the same reasons set forth in the Lead Opposition, the Amended Complaints in *Cataudella, Lau,* and *Parker* adequately state claims against the Supplemental Defendants.[1]

[1] In their discussion of the fact alleged in the original pleadings – but not in their argument – the Supplemental Defendants complain that Plaintiffs do not provide the names of their prescribing physicians, nor the precise dates on which they took each of the TRT products they allege they used. As the omission of this point from the "Argument" section of their brief signals, the Supplemental Defendants are apparently well aware that Plaintiffs are not required, under Rule 8 or otherwise, to provide this level of detail in their pleadings. The Supplemental Defendants are also likely well aware that, in coordinated multi-district proceedings such as these, details such as (footnote continues on next page)

## II. PLAINTIFFS SUFFICIENTLY PLEAD THEIR CLAIMS FOR FRAUD AND NEGLIGENT MISREPRESENTATION UNDER RULE 9(B)

The Supplemental Defendants also claim that Plaintiffs have failed to plead their fraud and misrepresentation claims with the requisite degree of particularity. Again, the Supplemental Defendants are wrong. Plaintiffs' Amended Complaints specifically identify the misrepresentations and omissions at the heart of their claims. First, Plaintiffs allege that each of the Supplemental Defendants misrepresented that "hypogonadism" and "low testosterone" were one and the same, and suggested that its product was approved to treat "low testosterone" untethered to an actual medical condition. As set forth above, Plaintiffs describe the specific advertising and marketing campaigns of each Supplemental Defendant. *See supra* pp. 1-7; *see also Cataudella* AC ¶¶ 7, 34, 42-48 (describing Endo's marketing); *Lau* AC ¶¶ 6, 41-51, 71-72 (describing Lilly's marketing); *Parker* AC ¶¶ 42-69 (describing Auxilium's marketing). Second, Plaintiffs allege that each of the Supplemental Defendants omitted, and failed to warn about, the dangers of TRT. *See Cataudella* AC ¶¶ 150-152; *Lau* AC ¶¶ 100-114; *Parker* AC ¶¶ 129-142. For the reasons set forth in the Lead Opposition, these allegations are sufficient to meet the requirements of Rule 9(b).

## III. PLAINTIFFS' CLAIMS FOR BREACH OF WARRANTY AND NEGLIGENT MISREPRESENTATION SHOULD NOT BE DISMISSED

The Supplemental Defendants, incorporating by reference arguments in the Defendants' main motion, ask this Court to address specific claims under Arizona, Florida, and Nevada law. For the reasons set forth in the Lead Opposition, this Court should decline to rule on specific variations of state law in each case. Such issues are best dealt with in the context of individual actions selected as bellwethers or otherwise being prepared for trial, at which point individual pleadings may properly be

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prescriber information and prescription dates are typically provided in Plaintiff Fact Sheets.

examined. Asking the Court to examine separate each of the hundreds or thousands of pleadings in this MDL, and to make rulings on each possible cause of action under the laws of each state, is an inefficient and inappropriate way to proceed in this MDL.

Nor do the Defendants' arguments have merit in any case. For the reasons set forth in Plaintiffs' Lead Opposition, the merger of state-law warranty claims into codified strict liability claims does not require dismissal of those claims; rather such claims may be deemed to have been pled under the relevant state statute. Nor, for the reasons set forth in Plaintiffs' Lead Opposition, should the Court dismiss the negligent misrepresentation pleaded in the *Parker* case. No Nevada case requires such dismissal, and, as explained in Plaintiffs' Lead Opposition, if confronted with the question, it is most likely that the Nevada Supreme Court would follow California law and permit plaintiff's claim in this circumstance.

## CONCLUSION

For the foregoing reasons, and for the reasons set forth in the Lead Opposition, this Court should deny in its entirety the Supplemental Motion to dismiss.